REMARKS

With this response, applicants cancel claims 18-22 and 24 without prejudice, amend claims 1, 8, 11, 12, 23, and 25-28, and add new claims 29-35. After amendment, claims 1-17, 23, and 25-35 are pending.

Claims 1, 8, 11, 12, and 23 are amended to correct typographical errors and to more clearly define the claimed subject matter. Support for the added limitation "associated with GDF-8" in claim 1 can be found in the specification at paragraph 29. Claims 25-28 are amended for clarity and to more clearly identify the claimed subject matter. Support for amino acids 20 to 138 of SEQ ID NO:3 can be found in the specification at paragraph 51, and support for sequences that are at least 80% identical to the ActRIIB sequence of SEQ ID NO:3 can be found at paragraph 47. Dependent claims 29-31 limit the percent identity of the sequences of independent claim 1, and are supported in the specification at paragraph 47, for example. Dependent claims 32-35, reciting specific modifications of the antibody Fc portion, are supported in the specification at paragraph 52, for example. No new matter is added by this amendment. Applicants respectfully ask the Examiner to enter the amendment.

Restriction Requirement

In this action, the Examiner required restriction between the following groups of claims:

Group I. Claims 1-17 and 23, drawn to a method for treatment or prevention of at least one degenerative disorder of muscle, bone, or glucose homeostasis, comprising administering an ActRIIB-Fc fusion protein to inhibit GDF-8 activity;

Group II. Claims 18-22, drawn to ActRIIB-Fc fusion proteins, nucleic acids encoding the same, and vectors and host cells comprising the nucleic acid;

Group III. Claim 24, drawn to a method for identifying inhibitors of GDF-8, comprising use of an ActRIIB-Fc fusion protein;

Group IV. Claim 25, drawn to a method for inhibiting GDF-8 activity, comprising contacting GDF-8 with a composition comprising an ActRIIB-Fc fusion protein;

Group V. Claim 26, drawn to a method for increasing muscle strength, comprising administering an ActRIIB-Fc fusion protein to inhibit GDF-8 activity;

Group VI. Claim 27, drawn to a method for increasing trabecular bone density, comprising administering an ActRIIB-Fc fusion protein to inhibit GDF-8 activity; and

Group VII. Claim 28, drawn to a method for increasing glucose tolerance, comprising administering an ActRIIB-Fc fusion protein to inhibit GDF-8 activity.

Applicants provisionally elect with traverse claims 1-17 and 23 of Group I. The Examiner further defines nineteen species of disorder from the group of claimed degenerative disorders of muscle, bone, or glucose homeostasis in Group I, and requires selection of one species at this time. In response, Applicants select muscular dystrophy as the species for initial examination.

Applicants believe that the restriction requirement between Groups I, IV, V, VI, and VII is improper. While the Examiner has alleged that the claims are drawn to independent and distinct inventions, he has not shown that it would be a serious burden to examine the claims together. The Examiner's attention is respectfully directed to M.P.E.P. § 803, which states:

> If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

In the Office Action, the Examiner fails to demonstrate why the joint examination of claims from Groups I, IV, V, VI, and VII would be a serious burden, other than to state

that the Groups are directed to methods that are divergent in materials and steps. The present invention relates to the use of ActRIIB fusion polypeptides to inhibit GDF-8 activity and thereby treat degenerative disorders of muscle, bone, or glucose homeostasis that are associated with GDF-8. Groups I, V, VI, and VII are all classified as class 514, subclass 2 and Group IV is classified as class 424, subclass 134.1. The claims of Groups I, V, VI, and VII all relate to the administration of ActRIIB fusion polypeptides in the same manner to interact with the same target (GDF-8). As such, Groups I, V, VI, and VII could all be examined with a single search. The claim of Group IV relates to contacting GDF-8 with an ActRIIB fusion polypeptide to bring about the inhibition of GDF-8. As such, a single search would allow examination of Groups I, IV, V, VI, and VII.

In the Office Action, the Examiner also alleges that the claims of Groups I, IV, V, VI, and VII are distinct, wherein each has different method steps, starting compounds, and goals, and are not required one for the other. Applicants respectfully disagree and direct the Examiner's attention to M.P.E.P. § 802, which states:

> Two or more inventions are related (i.e., not independent) if they are disclosed as connected in at least one of design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect.

Groups I, IV, V, VI, and VII are all connected in operation because they all relate to the use of ActRIIB fusion polypeptides to inhibit GDF-8 activity. Groups I, V, VI, and VII are further connected in operation because they all relate to the administration of ActRIIB fusion polypeptides to treat GDF-8 associated disorders by inhibiting GDF-8 activity.

Administration of an ActRIIB fusion polypeptide to inhibit GDF-8 activity (Groups I, V, VI, and VII) results in contacting GDF-8 with a composition comprising an ActRIIB fusion polypeptide, as supported in this application and set forth in claim 25 (Group IV).

In view of the foregoing remarks, Applicants submit that the Examiner has not established a case for serious burden of search nor has he established a case that the claims of Groups I, IV, V, VI, and VII are independent and distinct. Accordingly, Applicants respectfully request that the restriction requirement as to these groups be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 6, 2006

By: Mary K. Ferguson
Mary K. Ferguson
Reg. No. 51,675